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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,746	10/01/2001	Maurice Zauderer	1821.0060001/EKS/AJK	3613

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EXAMINER	
LUCAS, ZACHARIAH	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/966,746	ZAUDERER, MAURICE	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6,7 and 24-30* is/are pending in the application.

4a) Of the above claim(s) *24,26 and 28-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,7,25 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10-17-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-4, 6, 7, 24-30 are pending in the present application.

2. Claims 1-4. 6, and 7 were pending and rejected in the prior (Final) action mailed on December 16, 2004.

3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 17, 2005 has been entered. In the submission, the Applicant has amended claim 1, and added new claims 24 and 25.

Newly submitted claim 24 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The claim is drawn to the claimed methods wherein the gene products to be tested are up-regulated during mycobacterial infection. Previously, the claims were drawn either to gene products up-regulated during infections generally (in the previously generic claim 1), or to embodiments wherein the infection is a viral infection (see e.g., claim 4). However, in the present amendments, the Applicant has added new claim 24 (and amended claim 1) to read on an alternative embodiment to the viral species-embodiments wherein the infection is a mycobacterial infection. The new invention represents an unrelated invention to those previously claimed in that different functions are being performed in

screening for vaccine targets for viral infections than is performed in screening for vaccine targets for mycobacterial infections. Further, a search for the two inventions is not coextensive.

Newly added claims 26, and 28-30 are also drawn to inventions that are independent or distinct from the invention originally claimed for the following reasons: originally the claims were drawn to methods involving the identification of immune responses in general, or to CTL responses. New claims 26 and 28-30 now identify other types of immune responses that may be screened for, each of which performs a different function has a different mode of operation (i.e., the identification of antigens that induce different types of immune responses, and requiring the screening for such different responses). These various inventions are each unrelated to the originally claimed invention which involved screening only for a CTL response.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 24 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

It is noted that claim 1, as previously presented would have been generic to the different types of infections, and as originally presented would be generic to the various forms of immune response.

4. Claims 1-4, 6, 7, 25, and 27 are under consideration.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on October 17, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. **(Prior Rejection- Maintained)** Claims 1-4, 6, and 7 were rejected in the prior action under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to use the claimed method to identify potential vaccines for any infectious disease. The Applicant has added new claims 25 and 27. The rejection is extended to include each of claims 1-4, 6, 7, 25, and 27.

The Applicant traverses the rejection on the basis of the teachings in the Receptor Logic product information, and the teachings of Veronese and the Hunt Declaration. These arguments are not found persuasive.

With respect to the Receptor Logic reference, it is noted that although the Applicant asserts that the eIF4G gene product "has been identified as a potential CTL vaccine target." However, while the gene product is suggested as a potential vaccine target in cancer cells, the disclosure does not suggest the use of the protein as a target for the treatment of HIV. Further, while the reference does indicate that the protein is up-regulated in HIV infected cells, the teachings of the reference provide no guidance as to whether the induction of an immune

response against the protein would be useful in the treatment of the infection, or may result in further immunopathogenic responses. As was indicated in the prior actions, the art indicates that there is a significant amount of uncertainty in the use of such up-regulated proteins as targets for anti-infection vaccines. In particular, the teachings of the Herberts and the Hickman references indicate that while self antigens may be helpful in the clearance of infections, it is not clear if this would be the case, or if the use of such antigens would lead to immunopathogenic autoimmunity. Herberts, Human Immunol 64: 44-55, at 53; and Hickman, J Immunol 171:22-26, at 26. Thus, the fact that a protein has been identified as up-regulated in a host cell upon viral infection does not demonstrate that those in the art would have accepted that the claimed method would be useful for the identification of vaccine targets.

The Applicant's assertions regarding the teachings of Veronese and the Hunt declarations were previously considered and not found persuasive. See, Office Action of July 2004, pages 3-4; and the Office Action of December 2004, page 3. In short, neither the teachings of Veronese or of the Hunt declaration overcome the teachings of uncertainty in the art regarding the use of self-antigens to treat infectious diseases (as opposed to cancers).

It is also noted that the Applicant has cited in the October 2005 IDS an additional reference relevant to the claims. In the Könen-Waisman et al. (J Infect Dis 179: 403-13) reference, the art teaches a situation where the authors take advantage of a previously existing autoimmune response against a self-antigen to improve reactivity against a foreign antigen. Page 411. However, the reference does not suggest the use of anti-self vaccines in general, but suggests that the use of the particular antigen disclosed therein belongs to a limited set of self-antigens having certain immunological properties. Page 415. The cumulative teachings of these

references do not suggest the identification of up-regulated self-antigens as vaccine targets generally. Rather, the teachings suggest taking advantage of pre-existing, healthy, autoimmunity to supplement vaccination against pathogen antigens during the actual infection. Thus, the teachings of this reference, while indicating that in certain and unknown circumstances those in the art may take advantage or pre-existing autoimmunity, do not provide teachings contrary to those of the Herberts and Hickman references previously described.

The rejection is therefore maintained for the reasons of record and the reasons above.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. **(New Rejection)** Claims 1-3, 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Könen-Waisman et al. (J Infect Dis 179: 403-13). These claims are drawn to methods of screening for antigens comprising identifying human gene products that are up-regulated during an infection, and screening the gene products for an immune response in humans. Könen-Waisman teaches that the human hsp60 gene product has been identified as a protein that is up-regulated in inflammations near infections, and that the antigen is capable of inducing an immune response in people. Thus, the reference teaches the identification of a compound

comprising both the required steps described by the claims, and therefore anticipates the indicated claims.

Conclusion

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

JAMES HOUSEL 12/12/05
SUPERVISORY PATENT EXAMINER
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